

feeder study baseline). These changes were maintained or further improved during the open-label extension, such that significant improvements ($p < 0.001$ vs. feeder study baseline) were observed for darifenacin 7.5/15 mg in the same eight KHQ domains after a further 24 months of treatment. Darifenacin was well tolerated and the overall long-term safety profile was consistent to that observed in the 12 week phase III studies. **CONCLUSIONS:** Darifenacin significantly improves QoL in patients with OAB, with improvements maintained for 2 years during open-label treatment.

PUK29**DEVELOPMENT AND VALIDATION OF A COMPREHENSIVE SYMPTOM CHECKLIST IN URINARY INCONTINENCE**

Arnould B¹, Benmedjahed K², Amarenco G³, Coloby P⁴, Grise P⁵, Haab F⁶, Richard F⁷

¹Mapi Values, Lyon, Rhone, France; ²Mapi Values, Lyon, France;

³Rothschild hospital, Paris, France; ⁴René Dubos Hospital, Pontoise, France; ⁵CHU Charles Nicolle, Rouen, France; ⁶Ténon hospital, Paris, France; ⁷Pitié Salpêtrière Hospital, Paris, France

OBJECTIVE: To develop and validate a unique tool specific to urinary incontinence (UI) symptoms covering all types of incontinence among both men and women. **METHODS:** An Advisory Committee (AC) of 5 urologists was set up, involved at all stages of questionnaire development and validation. A test questionnaire was developed by AC with content validity being assessed simultaneously on 3 men, 4 women suffering from UI and 3 clinicians. Clinicians were asked to comment items' relevance and comprehensiveness; patients completed the scale and were asked to provide general comments regarding the scale and detailed comments regarding each element. The scale was redrafted and tested on 25 other patients. A longitudinal, multi-centre, anonymous, observational study was carried out to validate the scale. The scale was administrated by 21 urologists to 258 stable patients (206 UI sufferers and 52 not UI sufferers) until June 15th 2005. Patients filled in the scale, the ICIQ-SF and a diary twice at one-week interval and clinicians completed a medical form at baseline. **RESULTS:** The test scale contained 11 items covering urge, SUI, dysuria and pollakiuria. After initial cognitive debriefing and comments of patients and clinicians, 3 items were significantly modified. The pilot questionnaire still included 11 items. The validation study allowed assessing the internal consistency reliability, the test-retest reliability and the clinical validity of the scores. **CONCLUSION:** For the first time, psychometric properties were established for a simple-to-use, unique and UI specific symptom scale for men and women. This new instrument could be helpful for use in everyday medical practice and in clinical research.

PUK30**BENIGN PROSTATE HYPERPLASIA: RELATION BETWEEN IPSS, SPI AND QUALITY OF LIFE IPSS ITEM SCORES**

Perrin P¹, Cucherat M², Marionneau N³, Ruffion A¹, Taïeb C³, Myon E³

¹Lyon Sud Hospital, Pierre Bénite, France; ²University Teaching Hospital (CHU), Pierre Bénite, France; ³Pierre Fabre, Boulogne-Billancourt, France

OBJECTIVES: The International Prostatic Symptom Score (IPSS) evaluates the frequency of symptoms associated with lower urinary tract symptoms (LUTS). An eighth question (q8) evaluates the patient's overall satisfaction dealing with his urinary tract status but does not study in detail his bothersomeness. The SPI score (Symptom Problem Index) evaluates the degree of discomfort associated with each question on the IPSS. Our objective was to determine the relations between IPSS, SPI

and quality of life IPSS item (q8) scores. **METHODS:** A cohort of 907 male patients with BPH has been monitoring by French general practitioners. The IPSS and SPI self-administered questionnaires have been evaluated on the 722 patients with complete data. Relationships between SPI, IPSS and q8 have been investigated through the correlation between those scores and by showing the individual answers dispersion of IPSS and SPI scores when one was fixed. **RESULTS:** The mean IPSS score was 12.6 \pm 6.4, the mean SPI score was 12.2 \pm 6.5. The correlation coefficient between the IPSS and SPI scores was 0.70; the scores from the two rating scales showed a very high variability. Q8 was also weakly related to SPI ($r = 0.56$) and to IPSS ($r = 0.57$). The response to the question on quality of life corresponded to highly varying SPI and IPSS scores. **CONCLUSIONS:** IPSS and SPI questionnaires do not collect the same information. One scale cannot be replaced by another. Quality of life question of the IPSS questionnaire isn't enough to capture all the aspects of bothersomeness explored by the SPI questionnaire. Among patients suffering from LUTS, the joint use of the IPSS and SPI seems appropriate.

PUK31**DEVELOPMENT AND PILOT TESTING OF A NEW SCALE SPECIFICALLY MEASURING THE IMPACT OF STRESS URINARY INCONTINENCE (SUI) ON COMMON PHYSICAL ACTIVITIES OF DAILY LIFE**

Arnould B¹, Costa P², Dard S³, Heurtebize N⁴, Droumaguet C⁴, Bosio-Le Goux B⁴

¹Mapi Values, Lyon, Rhone, France; ²Caremeau Hospital, Nîmes, France; ³Mapi Values, Lyon, France; ⁴Lilly France, Suresnes, France

OBJECTIVE: Since stress incontinence episodes frequency is highly related to maintenance or avoidance of activities causing leakages, the additional benefit of therapeutic options might be difficult to capture. Our objective was to develop a new specific and sensitive endpoint to evaluate treatment effects in Stress Urinary Incontinence (SUI) in clinical trials. **METHODS:** A comprehensive list of efforts provoking leakages was established from a systematic literature review and 30 clinician interviews. The list was updated according to comments collected during 8 semi-structured clinicians interviews. Clinicians were asked about the relevance, comprehensiveness, and ability of the listed activities to capture changes. They also reported how their patients managed to control the risk of leakage. Twenty SUI women were asked to assess the relevance, importance, and applicability of each effort, to reword the list and to describe with their own words how they control the risk of leakage. The scale was finalised according to their comments. **RESULTS:** A list of 72 daily life efforts provoking leakage was set from 15 UI specific scales and 21 studies selected from the literature. The clinician interviews allowed to group similar concepts and to establish a shortlist containing the 15 most relevant efforts. Answer choices covered the occurrence of leakage, and various behaviour adaptation such as seeking help, taking precautions, muscular control, and avoiding situations. After validation of format, items, wording, and answer choices, by the patients, the pilot scale was produced. **CONCLUSION:** This self-reported scale allows SUI patients to accurately describe their control on leakage risk in daily life efforts. This highly specific instrument will allow clinicians to better assess the true impact of therapeutics on patients' life, in both clinical research and clinical practice. The scoring procedure and its properties will be assessed in a specific validation study.